EMADOC-1700519818-1976219

European Medicines Agency decision

EMA/PE/0000229144

of 21 March 2025

on the acceptance of a modification of an agreed paediatric investigation plan for respiratory syncytial virus stabilised prefusion F subunit vaccine (RSVpreF) (Abrysvo) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

Disclaimer

This decision does not constitute entitlement to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006.

Only the English text is authentic.

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The European Medicines Agency,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No. 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004[1],

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency[2],

Having regard to the European Medicines Agency's decision P/0255/2022 issued on 8 July 2022 and the decision P/0058/2023 issued on 24 January 2023,

Having regard to the application submitted by Pfizer Europe MA EEIG on 18 October 2024 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 31 January 2025, in accordance with Article 22 of Regulation (EC) No 1901/2006,

Having regard to Article 25 of Regulation (EC) No 1901/2006,

Whereas:

(1) The Paediatric Committee of the European Medicines Agency has given an opinion on the acceptance of changes to the agreed paediatric investigation plan and to the deferral.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan, including changes to the deferral.

[1] OJ L 378, 27.12.2006, p.1, as amended.
[2] OJ L 136, 30.4.2004, p. 1, as amended.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for respiratory syncytial virus stabilised prefusion F subunit vaccine (RSVpreF) (Abrysvo), including changes to the deferral, are hereby accepted in the scope set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices.

Article 2

This decision covers all conditions, indications, pharmaceutical forms, routes of administration, measures, timelines, waivers and deferrals, as agreed in the decision P/0202/2021 issued on 10 May 2021, including subsequent modifications thereof.

Article 3

This decision is addressed to Pfizer Europe MA EEIG, Boulevard De La Plaine 17, 1050 – Brussels, Belgium.

EMADOC-1700519818-1738112
Amsterdam, 31 January 2025

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan

EMA/PE/0000229144

Scope of the application

Active substance(s):

Respiratory syncytial virus stabilised prefusion F subunit vaccine (RSVpreF)

Invented name and authorisation status:

See Annex II

Condition(s):

Prevention of lower respiratory tract disease caused by respiratory syncytial virus

Pharmaceutical form(s):

Powder and solvent for solution for injection

Route(s) of administration:

Intramuscular use

Name/corporate name of the PIP applicant:

Pfizer Europe MA EEIG

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Pfizer Europe MA EEIG submitted to the European Medicines Agency on 18 October 2024 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/0255/2022 issued on 8 July 2022 and the decision P/0058/2023 issued on 24 January 2023.

The application for modification proposed changes to the agreed paediatric investigation plan and to the deferral.

The procedure started on 25 November 2024.

Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan have been modified.

Opinion

1. The Paediatric Committee, having assessed the application in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree to changes to the paediatric investigation plan and to the deferral in the scope set out in the Annex I of this opinion.

   The Paediatric Committee member of Norway agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the paediatric investigation plan and the subset(s) of the paediatric population and condition(s) covered by the waiver are set out in the Annex I.

This opinion is forwarded to the applicant and the Executive Director of the European Medicines Agency, together with its annexes and appendix.

Annex I

The subset(s) of the paediatric population and condition(s) covered by the waiver and the measures and timelines of the agreed paediatric investigation plan (PIP)

1. Waiver

1.1. Condition:

Prevention of lower respiratory tract disease caused by respiratory syncytial virus

The waiver applies to:

- the paediatric population from birth to less than 2 years of age;
- powder and solvent for solution for injection; intramuscular route;
- on the grounds that the specific medicinal product is likely to be unsafe.

2. Paediatric investigation plan

2.1. Condition:

Prevention of lower respiratory tract disease caused by respiratory syncytial virus

2.1.1. Indication(s) targeted by the PIP

Prevention of lower respiratory tract disease caused by respiratory syncytial virus

2.1.2. Subset(s) of the paediatric population concerned by the paediatric development

From 2 years to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Powder and solvent for solution for injection

2.1.4. Measures

Area	Description
Quality-related studies	Not applicable.
Non-clinical studies	Not applicable.
Clinical studies	**Study 1 (C3671016)** Open label, age-descending, dose-finding study of safety, tolerability and immunogenicity of respiratory syncytial virus stabilised prefusion F subunit vaccine (RSVpreF) in children from 2 years to less than 18 years of age. **Study 2 (C3671017)** Randomised, controlled study to evaluate the safety, tolerability, and immunogenicity of respiratory syncytial virus stabilised prefusion F subunit vaccine (RSVpreF) in children from 5 years to less than 18 years of age at high risk of RSV disease with an open label part to

	evaluate the safety, tolerability, and immunogenicity of respiratory syncytial virus stabilised prefusion F subunit vaccine (RSVpreF) in immunocompromised children from 5 years to less than 18 years of age. **Study 3 (C3671018)** *added in procedure EMA/PE/0000229144* Open-label dose-finding study to evaluate the safety, tolerability, and immunogenicity of respiratory syncytial virus stabilised prefusion F subunit vaccine (RSVpreF) in children from 2 years to less than 5 years of age, healthy or with high-risk chronic medical conditions (trisomy 21, cystic fibrosis, asthma, other chronic respiratory disease, neuromuscular diseases, cerebral palsy, congenital heart disease). **Study 4 (C3671073)** *added in procedure EMA/PE/0000229144* Randomised, controlled study to evaluate the safety, tolerability, and immunogenicity of respiratory syncytial virus stabilised prefusion F subunit vaccine (RSVpreF) in children from 2 years to less than 5 years of age healthy or at high risk of RSV-associated medically attended lower respiratory tract infection (MA-LRTI) with an open label part to evaluate the safety, tolerability, and immunogenicity of respiratory syncytial virus stabilised prefusion F subunit vaccine (RSVpreF) in immunocompromised children from 2 years to less than 5 years of age.
Extrapolation, modelling and simulation studies	Not applicable.
Other studies	Not applicable.
Other measures	Not applicable.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By October 2034
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

Condition(s) and authorised indication(s)

1. Prevention of lower respiratory tract disease caused by respiratory syncytial virus

Authorised indication(s):

- Active immunisation of individuals 60 years of age and older for the prevention of lower respiratory tract disease caused by RSV.
  - Invented name(s): Abrysvo
  - Authorised pharmaceutical form(s): Powder and solvent for solution for injection.
  - Authorised route(s) of administration: Intramuscular use
  - Authorised via centralised procedure.

2. Prevention of lower respiratory tract disease caused by respiratory syncytial virus via maternal immunisation

Authorised indication(s):

- Passive protection against lower respiratory tract disease caused by respiratory syncytial virus (RSV) in infants from birth through 6 months of age following maternal immunisation during pregnancy.
  - Invented name(s): Abrysvo
  - Authorised pharmaceutical form(s): Powder and solvent for solution for injection.
  - Authorised route(s) of administration: Intramuscular use
  - Authorised via centralised procedure.